

submission of the TRICARE pharmaceutical utilization data needed to calculate the refund before the refund payment is due. The basis of the refund will be the difference between the average non-Federal price of the drug sold by the manufacturer to wholesalers, as represented by the most recent annual non-Federal average manufacturing prices (non-FAMP) (reported to the Department of Veterans Affairs (VA)) and the corresponding FCP or, in the discretion of the manufacturer, the difference between the FCP and direct commercial contract sales prices specifically attributable to the reported TRICARE paid pharmaceuticals, determined for each applicable NDC listing. The current annual FCP and the annual non-FAMP from which it was derived will be applicable to all prescriptions filled during the calendar year.

(iii) A refund due under this paragraph (q) is subject to section 199.11 of this part and will be treated as an erroneous payment under that section.

(A) A manufacturer may under § 199.11 of this part request waiver or compromise of a refund amount due under 10 U.S.C. 1074g(f) and this paragraph (q).

(B) During the pendency of any request for waiver or compromise under subparagraph (q)(3)(iii)(A) of this section, a manufacturer's written agreement under paragraph (q)(2) shall be deemed to exclude the matter that is the subject of the request for waiver or compromise. In such cases the agreement, if otherwise sufficient for the purpose of the condition referred to in paragraph (q)(2), will continue to be sufficient for that purpose. Further, during the pendency of any such request, the matter that is the subject of the request shall not be considered a failure of a manufacturer to honor an agreement for purposes of paragraph (q)(4).

(C) In addition to the criteria established in § 199.11 of this section, a request for waiver may also be premised on the voluntary removal by the manufacturer in writing of a drug from coverage in the TRICARE Pharmacy Benefit Program.

(iv) In the case of disputes by the manufacturer of the accuracy of TMA's utilization data, a refund obligation as

to the amount in dispute will be deferred pending good faith efforts to resolve the dispute in accordance with procedures established by the Director, TMA. If the dispute is not resolved within 60 days, the Director, TMA will issue an initial administrative decision and provide the manufacturer with opportunity to request reconsideration or appeal consistent with procedures under § 199.10 of this part. When the dispute is ultimately resolved, any refund owed relating to the amount in dispute will be subject to an interest charge from the date payment of the amount was initially due, consistent with § 199.11 of this part.

(4) *Remedies.* In the case of the failure of a manufacturer of a covered drug to make or honor an agreement under this paragraph (q), the Director, TMA, in addition to other actions referred to in this paragraph (q), may take any other action authorized by law.

(5) *Beneficiary transition provisions.* In cases in which a pharmaceutical is removed from the uniform formulary or designated for preauthorization under paragraph (q)(2) of this section, the Director, TMA may for transitional time periods determined appropriate by the Director or for particular circumstances authorize the continued availability of the pharmaceutical in the retail pharmacy network or in MTF pharmacies for some or all beneficiaries as if the pharmaceutical were still on the uniform formulary.

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§ 199.22 TRICARE Retiree Dental Program (TRDP).

(a) *Purpose.* The TRDP is a premium based indemnity dental insurance coverage program that will be available to retired members of the Uniformed Services, their dependents, and certain other beneficiaries, as specified in paragraph (d) of this section. The TRDP is authorized by 10 U.S.C. 1076c.

(b) *General provisions.* (1) At a minimum, benefits are the diagnostic services, preventive services, basic restorative services (including endodontics), oral surgery services, and emergency services specified in paragraph (f)(1) of

this section. Additional services comparable to those contained in paragraph (e)(2) of §199.13 may be covered pursuant to benefit policy decisions made by the Director, TRICARE Management Activity, or designee.

(2) Premium costs for this coverage will be paid by the enrollee.

(3) *Geographic scope.* (i) The TRDP is applicable to authorized providers in the 50 United States and the District of Columbia, Canada, Puerto Rico, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and the U.S. Virgin Islands.

(ii) The Assistant Secretary of Defense (Health Affairs) (ASD (HA)) may extend the TRDP to geographic areas other than those specified in paragraph (b)(3)(i) of this section. In extending the TRDP overseas, the ASD (HA) is authorized to establish program elements, methods of administration, and payment rates and procedures that are different from those in effect for the areas specified in paragraph (b)(3)(i) of this section to the extent the ASD (HA), or designee, determines necessary for the effective and efficient operation of the TRDP. These differences may include, but are not limited to, specific provisions for preauthorization of care, varying licensure and certification requirements for foreign providers, and other differences based on limitations in the availability and capabilities of the Uniformed Services overseas dental treatment facilities and a particular nation's civilian sector providers in certain areas. The Director, TRICARE Management Activity shall issue guidance, as necessary, to implement the provisions of this paragraph. TRDP enrollees residing in overseas locations will be eligible for the same benefits as enrollees residing in the continental United States, although dental services may not be available or accessible in all locations.

(4) Except as otherwise provided in this section or by the Assistant Secretary of Defense (Health Affairs) or designee, the TRDP is administered in a manner similar to the TRICARE Dental Program under §199.13 of this part.

(5) The TRDP shall be administered through a contract.

(c) Except as may be specifically provided in this section, to the extent terms defined in §199.2 and §199.13(b) are relevant to the administration of the TRICARE Retiree Dental Program, the definitions contained in §199.2 and §199.13(b) shall apply to the TRDP as they do to TRICARE/CHAMPUS and the TRICARE Dental Program.

(d) *Eligibility and enrollment*—(1) *Eligibility.* Enrollment in the TRICARE Retiree Dental Program is open to:

(i) Members of the Uniformed Services who are entitled to retired pay, or former members of the armed forces who are Medal of Honor recipients and who are not otherwise entitled to dental benefits;

(ii) Members of the Retired Reserve under the age of 60;

(iii) Eligible dependents of a member described in paragraph (d)(1)(i) or paragraph (d)(1)(ii) of this section who are covered by the enrollment of the member;

(iv) Eligible dependents of a member described in paragraph (d)(1)(i) or paragraph (d)(1)(ii) of this section when the member is not enrolled in the program and the member meets at least one of the conditions in paragraphs (d)(1)(iv)(A) through (C) of this section. Already enrolled members must satisfy any remaining enrollment commitment prior to enrollment of dependents becoming effective under this paragraph, at which time the dependent-only enrollment will continue on a voluntary basis as specified in paragraph (d)(4) of this section. Members must provide documentation to the TRDP contractor giving evidence of compliance with paragraphs (d)(1)(iv)(A), (B), or (C) of this section at the time of application for enrollment of their dependents under this paragraph.

(A) The member is enrolled under Section 1705 of Title 38, United States Code, to receive ongoing, comprehensive dental care from the Department of Veterans Affairs pursuant to Section 1712 of Title 38, United States Code, and 38 CFR 17.93, 17.161, or 17.166. Authorization of such dental care must be confirmed in writing by the Department of Veterans Affairs.

(B) The member is enrolled in a dental plan that is available to the member as a result of employment of the

member that is separate from the Uniformed Service of the member, and the dental plan is not available to dependents of the member as a result of such separate employment by the member. Enrollment in this dental plan and the exclusion of dependents from enrollment in the plan must be confirmed by documentation from the member's employer or the dental plan's administrator.

(C) The member is prevented by a current and enduring medical or dental condition from being able to obtain benefits under the TRDP. The specific medical or dental condition and reason for the inability to use the program's benefits over time, if not apparent based on the condition, must be documented by the member's physician or dentist.

(v) The unremarried surviving spouse and eligible child dependents of a deceased member who died while in status described in paragraph (d)(1)(i) or paragraph (d)(1)(ii) of this section; the unremarried surviving spouse and eligible child dependents who receive a surviving spouse annuity; or the unremarried surviving spouse and eligible child dependents of a deceased member who died while on active duty for a period of more than 30 days and whose eligible dependents are not eligible or no longer for the TRICARE Dental Program.

NOTE TO PARAGRAPHS (d)(1)(iii), (d)(1)(iv), AND (d)(1)(v): Eligible dependents of Medal of Honor recipients are described in § 199.3(b)(2)(i) (except for former spouses) and § 199.3(b)(2)(ii) (except for a child placed in legal custody of a Medal of Honor recipient under § 199.3(b)(2)(ii)(H)(4)).

(2) *Notification of eligibility.* The contractor will notify persons eligible to receive dental benefits under the TRICARE Retiree Dental Program.

(3) *Election of coverage.* In order to initiate dental coverage, election to enroll must be made by the member or eligible dependent. Enrollment in the TRICARE Retiree Dental Program is voluntary and will be accomplished by submission of an application to the TRDP contractor.

(4) *Enrollment periods*—(i) *Enrollment period for basic benefits.* The initial enrollment for the basic dental benefits described in paragraph (f)(1) of this sec-

tion shall be for a period of 24 months followed by month-to-month enrollment as long as the enrollee remains eligible and chooses to continue enrollment. An enrollee's disenrollment from the TRDP at any time for any reason, including termination for failure to pay premiums, is subject to a lockout period of 12 months. After any lockout period, eligible individuals may elect to reenroll and are subject to a new initial enrollment period. The enrollment periods and conditions stipulated in this paragraph apply only to the basic benefit coverage described in paragraph (f)(1) of this section. Effective with the implementation of an enhanced benefit program, new enrollments for basic coverage will cease. Enrollees in the basic program at that time may continue their enrollment for basic coverage, subject to the applicable provisions of this section, as long as the contract administering that coverage is in effect.

(ii) *Enrollment period for enhanced benefits.* The initial enrollment period for enhanced benefit coverage described in paragraph (f)(2) of this section shall be established by the Director, TMA, or designee, to be a period of not less than 12 months and not more than 24 months. The initial enrollment period shall be followed by renewal enrollment periods of up to 12 months as long as the enrollee chooses to continue enrollment and remains eligible. An enrollee who chooses not to continue enrollment upon completion of an enrollment period may re-enroll at any time. However, an enrollee who is disenrolled from the TRDP before completion of an initial or subsequent enrollment period for reasons other than those in paragraphs in (d)(5)(ii)(A) and (B) of this section shall incur a lockout period of 12 months before re-enrollment can occur. Former enrollees who re-enroll following a lockout period or following a period of disenrollment after completion of an enrollment period must comply with all provisions that apply to new enrollees, including a new enrollment commitment.

(5) *Termination of coverage*—(i) *Involuntary termination.* TRDP coverage is terminated when the member's entitlement to retired pay is terminated, the member's status as a member of the

Retired Reserve is terminated, a dependent child loses eligible child dependent status, or a surviving spouse remarries.

(ii) *Voluntary termination.* All enrollee requests for termination of TRDP coverage before the completion of an enrollment period shall be submitted to the TRDP contractor for determination of whether the enrollee qualifies to be disenrolled under paragraphs (d)(5)(ii)(A) or (B) of this section.

(A) *Enrollment grace period.* Regardless of the reason, TRDP coverage shall be cancelled, or otherwise terminated, upon request from an enrollee if the request is received by the TRDP contractor within 30 calendar days following the enrollment effective date and there has been no use of TRDP benefits under the enrollment during that period. If such is the case, the enrollment is voided and all premium payments are refunded. However, use of benefits during this 30-day enrollment grace period constitutes acceptance by the enrollee of the enrollment and the enrollment period commitment. In this case, a request for termination of enrollment under paragraph (d)(5)(ii)(A) of this section will not be honored, and premiums will not be refunded.

(B) *Extenuating circumstances.* Under limited circumstances, TRDP enrollees shall be disenrolled by the contractor before the completion of an enrollment period commitment upon request by an enrollee if the enrollee submits written, factual documentation that independently verifies that one of the following extenuating circumstances occurred during the enrollment period. In general, the circumstances must be unforeseen and long-term and must have originated after the effective date of TRDP coverage.

(1) The enrollee is prevented by a serious medical condition from being able to utilize TRDP benefits.

(2) The enrollee would suffer severe financial hardship by continuing TRDP enrollment; or

(3) Any other circumstances which the Secretary considers appropriate.

(C) *Effective date of voluntary termination.* For cases determined to qualify for disenrollment under the grace period provisions in paragraph (d)(5)(ii)(A) of this section, enrollment

is completely nullified effective from the beginning date of coverage. For cases determined to qualify for disenrollment under the extenuating circumstances provisions in paragraph (d)(5)(ii)(B) of this section, the effective date of disenrollment is the first of the month following the contractor's initial determination on the disenrollment request or the first of the month following the last use of TRDP benefits under the enrollment, whichever is later.

(D) *Appeal process for denied voluntary enrollment termination.* An enrollee has the right to appeal the contractor's determination that a disenrollment request does not qualify under paragraphs (d)(5)(ii)(A) or (B) of this section. The enrollee may appeal that determination by submitting a written appeal to the TMA, Office of Appeals and Hearings, with a copy of the contractor's determination notice and relevant documentation supporting the disenrollment request. This appeal must be received by TMA within 60 days of the date on the contractor's determination notice. The burden of proof is on the enrollee to establish affirmatively by substantial evidence that the enrollee qualifies to be disenrolled under paragraphs (d)(5)(ii)(A) or (B) of this section. TMA will issue written notification to the enrollee and the contractor of its appeal determination within 60 days from the date of receipt of the appeal request. That determination is final.

(6) *Continuation of dependents' enrollment upon death of enrollee.* Coverage of a dependent in the TRDP under an enrollment of a member or surviving spouse who dies during the period of enrollment shall continue until the end of that period and may be renewed by (or for) the dependent, so long as the premium paid is sufficient to cover continuation of the dependent's enrollment. Coverage may be terminated when the premiums paid are no longer sufficient to cover continuation of the enrollment.

(e) *Premium payments.* Persons enrolled in the dental plan will be responsible for paying the full cost of the premiums in order to obtain the dental insurance.

(1) *Premium payment method.* The premium payment may be collected pursuant to procedures established by the Assistant Secretary of Defense (Health Affairs) or designee.

(2) *Effects of failure to make premium payments.* Failure to make premium payments will result in the enrollee's disenrollment from the TRDP and a lockout period of 12 months. Following this period of time, eligible individuals will be able to re-enroll.

(3) *Member's payment of premiums.* The cost of the TRDP monthly premium will be paid by the enrollee. Interested beneficiaries may contact the dental contractor-insurer to obtain the enrollee premium cost.

(f) *Plan benefits.* The Director, TRICARE Management Activity, or designee, may modify the services covered by the TRDP to the extent determined appropriate based on developments in common dental care practices and standard dental programs. In addition, the Director, TRICARE Management Activity, or designee, may establish such exclusions and limitations as are consistent with those established by dental insurance and prepayment plans to control utilization and quality of care for the services and items covered by the TRDP.

(1) The minimum TRDP benefit is basic dental care to include diagnostic services, preventive services, restorative services, endodontic services, periodontic services, oral surgery services, and other general services. The following is the minimum TRDP covered dental benefit:

- (i) *Diagnostic services.*
 - (A) Clinical oral examinations.
 - (B) Radiographs and diagnostic imaging.
 - (C) Tests and laboratory examinations.
- (ii) *Preventive services.*
 - (A) Dental prophylaxis.
 - (B) Topical fluoride treatment (office procedure).
 - (C) Sealants.
 - (D) Other preventive services.
 - (E) Space maintenance.
- (iii) *Restorative services.*
 - (A) Amalgam restorations.
 - (B) Resin-based composite restorations.
 - (C) Other restorative services.

(iv) *Endodontic services.*

- (A) Pulp capping.
- (B) Pulpotomy and pulpectomy.
- (C) Root canal therapy.
- (D) Apexification and recalcification procedures.
- (E) Apicoectomy and periradicular services.
- (F) Other endodontic procedures.
- (v) *Periodontic Services.*
 - (A) Surgical services.
 - (B) Periodontal services.
- (vi) *Oral surgery.*
 - (A) Extractions.
 - (B) Surgical extractions.
 - (C) Alveoloplasty.
 - (D) Biopsy.
 - (E) Other surgical procedures.
- (vii) *Other general services.*
 - (A) Palliative (emergency) treatment of dental pain.
 - (B) Therapeutic drug injection.
 - (C) Other drugs and/or medicaments.
 - (D) Treatment of postsurgical complications.

(2) *Enhanced benefits.* In addition to the minimum TRDP services in paragraph (f)(1) of this section, other services that are comparable to those contained in paragraph (e)(2) of § 199.13 may be covered pursuant to TRDP benefit policy decisions made by the Director, OCHAMPUS, or designee. In general, these include additional diagnostic and preventive services, major restorative services, prosthodontics (removable and fixed), additional oral surgery services, orthodontics, and additional adjunctive general services (including general anesthesia and intravenous sedation). Enrollees in the basis plan will be given an enrollment option at the time the enhanced plan is implemented.

(3) *Alternative course of treatment policy.* The Director, TRICARE Management Activity, or designee, may establish, in accordance with generally accepted dental benefit practices, an alternative course of treatment policy which provides reimbursement in instances where the dentist and TRDP enrollee select a more expensive service, procedure, or course of treatment than is customarily provided. The alternative course of treatment policy must meet the following conditions:

- (i) The service, procedure, or course of treatment must be consistent with

sound professional standards of generally accepted dental practice for the dental condition concerned.

(ii) The service, procedure, or course of treatment must be a generally accepted alternative for a service or procedure covered by the TRDP for the dental condition.

(iii) Payment for the alternative service or procedure may not exceed the lower of the prevailing limits for the alternative procedure, the prevailing limits or dental plan contractor's scheduled allowance for the otherwise authorized benefit procedure for which the alternative is substituted, or the actual charge for the alternative procedure.

(g) *Maximum coverage amounts.* Each enrollee is subject to an annual maximum coverage amount for non-orthodontic dental benefits and, if an orthodontic benefit is offered, a lifetime maximum coverage amount for orthodontics as established by the Director, TRICARE Management Activity, or designee.

(h) *Annual notification of rates.* TRDP premiums will be determined as part of the competitive contracting process. Information on the premium rates will be widely distributed.

(i) *Authorized providers.* The TRDP enrollee may seek covered services from any provider who is fully licensed and approved to provide dental care in the state where the provider is located.

(j) *Benefit payment.* Enrollees are not required to utilize the special network of dental providers established by the TRDP contractor. For enrollees who do use these network providers, however, providers shall not balance bill any amount in excess of the maximum payment allowable by the TRDP. Enrollees using non-network providers may balance billed amounts in excess of allowable charges. The maximum payment allowable by the TRDP (minus the appropriate cost-share) will be the lesser of:

(1) Billed charges; or

(2) Usual, Customary and Reasonable rates, in which the customary rate is calculated at the 50th percentile of billed charges in that geographic area, as measured in an undiscounted charge profile in 1995 or later for that geo-

graphic area (as defined by three-digit zip code).

(k) *Appeal procedures.* All levels of appeal established by the contractor shall be exhausted prior to an appeal being filed with the TMA. Procedures comparable to those established for appeal of benefit determinations under § 199.10 of this part shall apply together with the procedures for appeal of voluntary disenrollment determinations described in paragraph (d)(5)(ii)(D) of this section.

(l) *Preemption of State laws.* (1) Pursuant to 10 U.S.C. 1103, the Department of Defense has determined that in the administration of chapter 55 of title 10, U.S. Code, preemption of State and local laws relating to health insurance, prepaid health plans, or other health care delivery or financing methods is necessary to achieve important Federal interests, including but not limited to the assurance of uniform national health programs for military families and the operation of such programs at the lowest possible cost to the Department of Defense, that have a direct and substantial effect on the conduct of military affairs and national security policy of the United States. This determination is applicable to the dental services contracts that implement this section.

(2) Based on the determination set forth in paragraph (l)(1) of this section, any State or local law or regulation pertaining to health or dental insurance, prepaid health or dental plans, or other health or dental care delivery, administration, and financing methods is preempted and does not apply in connection with the TRICARE Retiree Dental Program contract. Any such law, or regulation pursuant to such law, is without any force or effect, and State or local governments have no legal authority to enforce them in relation to the TRICARE Retiree Dental Program contract. (However, the Department of Defense may, by contract, establish legal obligations on the part of the TRICARE Retiree Dental Program contractor to conform with requirements similar to or identical to requirements of State or local laws or regulations).

(3) The preemption of State and local laws set forth in paragraph (l)(2) of this

section includes State and local laws imposing premium taxes on health or dental insurance carriers or underwriters or other plan managers, or similar taxes on such entities. Such laws are laws relating to health insurance, prepaid health plans, or other health care delivery or financing methods, within the meaning of section 1103. Preemption, however, does not apply to taxes, fees, or other payments on net income or profit realized by such entities in the conduct of business relating to DoD health services contracts, if those taxes, fees or other payments are applicable to a broad range of business activity. For the purposes of assessing the effect of Federal preemption of State and local taxes and fees in connection with DoD health and dental services contracts, interpretations shall be consistent with those applicable to the Federal Employees Health Benefits Program under 5 U.S.C. 8909(f).

(m) *Administration.* The Assistant Secretary of Defense (Health Affairs) or designee may establish other rules and procedures for the administration of the TRICARE Retiree Dental Program.

[62 FR 66993, Dec. 23, 1997, as amended at 65 FR 48913, Aug. 10, 2000; 65 FR 49492, Aug. 14, 2000; 66 FR 9658, Feb. 9, 2001; 67 FR 4354, Jan. 30, 2002; 67 FR 15725, Apr. 3, 2002; 72 FR 54213, Sept. 24, 2007; 72 FR 64537, Nov. 16, 2007; 73 FR 59504, Oct. 9, 2008]

§ 199.23 Special Supplemental Food Program.

(a) *General provisions.* This section prescribes guidelines and policies for the delivery and administration of the Special Supplemental Food Program for Women, Infants, and Children Overseas (WIC Overseas Program). The purpose of the WIC Overseas Program is to provide supplemental foods and nutrition education, at no cost, to eligible persons and to serve as an adjunct to good health care during critical times of growth and development, in order to prevent the occurrence of health problems, including drug and other substance abuse, and to improve the health status of program participants. The benefit is similar to the benefit provided under the U.S. Department of Agriculture (USDA) administered

Women, Infants, and Children (WIC) Program.

(b) *Definitions.* For most definitions applicable to the provisions of this section, refer to sec. 199.2. The following definitions apply only to this section:

(1) *Applicant.* Pregnant women, breastfeeding women, postpartum women, infants, and children who are applying to receive WIC Overseas benefits, and the breastfed infants of applicant breastfeeding women. This term also includes individuals who are currently participating in the Program but are re-applying because their certification is about to expire.

(2) *Breastfeeding women.* Women up to 1-year postpartum who are breastfeeding their infants. Their eligibility will end on the last day of the month of their infant's first birthday.

(3) *Certification.* The implementation of criteria and procedures to assess and document each applicant's eligibility for the Program.

(4) *Children.* Persons who have had their first birthday but have not yet attained their fifth birthday. Their eligibility will end on the last day of the month of their fifth birthday.

(5) *Competent Professional Authority (CPA).* An individual on the staff of the WIC Overseas office authorized to determine nutritional risk, prescribe supplemental foods, and design nutrition education programs. The following are authorized to serve as a competent professional authority: physicians, nutritionists, registered nurses, and dietitians may serve as a competent professional authority. Additionally, a CPA may be other persons designated by the regional program manager who meet the definition of CPA prescribed by the USDA as being professionally competent to evaluate nutritional risk. The definition also applies to an individual who is not on the staff of the WIC Overseas office but who is qualified to provide data upon which nutritional risk determinations are made by a competent professional authority on the staff of the local WIC Overseas office.

(6) *Contract brand.* The brand of a particular food item that has been competitively selected by the DoD to be the exclusive supplier of that type of food item to the program.